Spievack Reference

Claims 1-5, 7, 10, 15, 17, 34 and 43 stand rejected under 35 USC 102(b) as being anticipated by Spievack et al., U.S. patent 5,871,484, issued February 16, 1999 ("Spievack"). Applicants respectfully traverse this rejection.

Generally, Spievack discloses a bone fastener device adapted to deliver biologically active substances (e.g., therapeutic drugs, such as antibiotics, analgesics, bone morphogenic proteins, DNA, chemotherapy drugs and angiogenesis factors) to a bone site. (*See*, Spievack Abstract) The device includes a collagen sponge 30 located in a hollow center cavity 25 which is saturated with the biologically active substance. A physician depresses an activation handle 38 to compress sponge 30 which in turn, forces the biologically active substance out of the device through vias 22 (Column 3, lines 23-67). The device further includes a catheter 34 or cannulation 53 which carries the biologically active substance to and from the sponge 30.

In contrast, Applicants' claim 1 recites a device "for forming fixation masses" comprising a "cannula configured to receive a fixation substance;" and "at least one slot . . . for delivery of said fixation substance in close proximity to a cortex portion of said bone."

In addition, Applicants' independent claim 10 recites "a bone anchoring device" comprising, among other elements, "a cannula suitably configured to internally deliver an anchoring substance". . . "to form an anchoring mass. . ." As the Examiner acknowledged on Page 4 of the Office Action, Spievack fails to disclose "a device [that] can be used with a fixation substance to form fixation masses in compliance with the slots of their device. They [Spievack] also do not disclose that the slots deliver a fixation substance to inner and outer cortex portions, and they do not disclose a hardening substance or bone cement."

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Moreover, configuring the device taught by Spievack, and in particular, the cannula, for delivery of a fixation substance is not contemplated by Spievack, because Spievack does not disclose or even suggest a device for forming masses about the bone.

Spievack fails to disclose, teach or suggest each and every element of independent claims 1 and 10. Therefore, Applicants submit that claims 1 and 10 and claims 2-5, 7, 15, 17, 34 and 43, which variously depend from 1 and 10, are patentably distinct over the disclosure of Spievack. Applicants respectfully request the withdrawal of the Section 102 rejection with respect to claims 1-5, 7, 10, 15, 17, 34 and 43.

Tronzo Reference

Claims 26-28, 30-33 and 37-39 stand rejected under 35 USC 103(a) as being unpatentable over Tronzo, U.S. patent 4,653,489 issued March 31, 1987 ("Tronzo"). Applicants respectfully traverse this rejection.

Generally, Tronzo discloses a fenestrated hollow sliding hip screw for augmenting fixation by injecting bone cement for enhanced fixation. (*See*, Tronzo Abstract; column 3 lines 1-3). The device includes an elongated plate 34 of a shape conforming to the outer face of a thigh bone 24. The plate 34 is attached to thigh bone 24 with a plurality of screws 38. (Column 3, lines 39-43). Fenestrations 40, 42 and 44 "*do not go into the distal threads. . ., which would jeopardize the sliding mechanism.*" (Column 4, lines 34-37).

In contrast, Applicants' amended independent claims, in particular, claims 23 and 35, in which claims 24-28 and 31-33 depend respectfully, recite slots located in *both the proximal and distal portions* of the device. As illustrated in Figure 2 of Tronzo, fenestrations 40, 42 and 44 and cement masses 52 are concentrated at only one end (the distal end) of the device. In fact, Tronzo discloses that cement *is only* injected into the femoral head "to prevent any cement from

flowing around the barrel of the screw, which would prevent subsequent sliding." (Column 4, lines 64-67).

As the Examiner agreed during the Interviews, Tronzo fails to disclose slots in both the proximal and distal portions of the device. Moreover, Tronzo neither teaches nor suggests including slots at both ends of the device because the cement disposed through a slot located near the sliding mechanism (opposite end) would *jeopardize* the sliding mechanism.

With respect to claims 30-33, Applicants independent claim 30 recites "an anchor for an internal fixation device in a *pedicle bone*." Upon review of the device disclosed in Tronzo, including elongated plate 34 and screws 38, it is highly unlikely that the Tronzo device could ever be used in a pedicle bone. Moreover, Tronzo neither teaches, suggests, or discloses that the device may be modified to "anchor an internal fixation device in a pedicle bone." In fact, Tronzo only discloses and claims a hip screw and discloses that a "*sequenced practiced cementing technique must be utilized and a strict sequence of steps must be followed. . .according to the invention.*" (Column 4 line 49 through column 5 line 3). Applicants submit that the *strict sequence of steps* does not include a technique which is conducive to "an anchor for an internal fixation device in a *pedicle bone*."

Therefore, in light of the above remarks, Applicants submit that claims 26-28, 30-33 and 37-39 are patentably distinct over the disclosure of Tronzo and respectfully request the withdrawal of the Section 103 rejection.

Claims 11, 12, 18, 19, 25, 41, 42 and 44-47 stand rejected under 35 USC 103(a) as being unpatentable over Spievack in view of Tronzo. Applicants respectfully traverse this rejection.

The Examiner proposes that it would be obvious, in view of Tronzo, to modify the device of Spievack so that it could be used to inject an anchoring substance into a bone; for delivery of

bone cement through slots to form fixation masses within a bone; and it is a design choice to apply the cement to any bone portions requiring fixation, including inner and outer cortices. (Office Action Page 5). Applicants respectfully disagree.

During the Interviews, the Examiner agreed that the "sponge design" disclosed by Spievack makes it unlikely, if even possible, that the Spievack device can deliver "an anchoring substance into a bone." Therefore, Spievack can not be modified to "deliver a bone cement through slots to form a fixation mass within a bone," as suggested by the Examiner, regardless of the point of fixation.

In addition, the Examiner agreed that Tronzo fails to teach, suggest, or disclose applying cement to "any bone portion requiring fixation," but rather, Tronzo clearly teaches *only* delivering cement to the end of the device. Furthermore, Tronzo clearly discloses that "the cement thus injected *does not flow between the fracture fragments*." (Column 4, line 37-39). Thus, Tronzo *fails to disclose* applying cement to any bone portion requiring fixation. In contrast to Tronzo, Spievack necessarily discloses delivering biologically active substance near the "bone site" to treat the site. (*See generally*, Spievack column 3). Therefore, the combination of Speivack and Tronzo is improper and there is no basis, suggestion, or motivation to combine the two references as suggested by the Examiner.

Therefore, Applicants submit that claims 11, 12, 18, 19, 25, 41, 42 and 44-47 are patentably distinct over the proposed combination of Spievack and Tronzo and respectfully request the withdrawal of the Section 103 rejection.

CONCLUSION

In view of the discussions with the Examiner during the October 6, 2000 and October 16, 2000 Interviews and the foregoing amendments and remarks, Applicants respectfully request the

withdrawal of the Sections 102 and 103 rejections as to the remaining pending claims. Applicants submit that all of the pending claims fully comply with 35 USC 112 and are allowable over the cited art of record. Reconsideration of the application is respectfully requested. Applicants invite the Examiner to telephone the undersigned if he has any questions or suggestions which will expedite this application to allowance.

Respectfully submitted,

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